

AMENDED IN ASSEMBLY SEPTEMBER 12, 2001  
AMENDED IN ASSEMBLY SEPTEMBER 10, 2001  
AMENDED IN ASSEMBLY SEPTEMBER 6, 2001  
AMENDED IN ASSEMBLY AUGUST 30, 2001  
AMENDED IN ASSEMBLY AUGUST 28, 2001  
AMENDED IN ASSEMBLY AUGUST 20, 2001  
AMENDED IN ASSEMBLY JULY 19, 2001

**SENATE BILL**

**No. 293**

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**Introduced by Senators Torlakson and Figueroa**

February 16, 2001

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An act to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. Pharmacies: injectable sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state. Existing law regulates controlled substances, dangerous drugs, and dangerous devices. This bill would appropriate \$580,000 from the Pharmacy Board Contingent Fund for purposes of the bill.

This bill would authorize the board, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain

from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety. The bill would implement quality assurance methods regarding the compounding of injectable sterile drug products. The bill would require the board to adopt necessary regulations regarding injectable sterile drug products. The bill would require specified pharmacies to obtain a license from the board in order to prepare injectable sterile drug products. The bill would provide that the reconstitution of a sterile powder would not require a license if specified conditions are met. By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

This bill would provide that a violation of the bill or regulations adopted pursuant to it would be subject to a fine of up to \$2,500. These fines would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning injectable sterile drug products, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: <sup>2</sup>/<sub>3</sub>. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. It is the intent of the Legislature in enacting this
- 2 act to increase the regulatory scrutiny of the compounding of
- 3 sterile injectable drug products in pharmacies in order to improve
- 4 public safety. The compounding of injectable sterile drug products
- 5 in pharmacies benefits patients throughout California and is an
- 6 essential health care service.
- 7 Effective July 1, 2002, the sum of five hundred eighty thousand
- 8 dollars (\$580,000) is hereby appropriated from the Pharmacy
- 9 Board Contingent Fund to the California State Board of Pharmacy



1 for the costs associated with the implementation of this act,  
2 including, but not limited to, the salaries and benefits of the  
3 employees required to implement this act.

4 SEC. 2. Article 7.5 (commencing with Section 4127) is added  
5 to Chapter 9 of Division 2 of the Business and Professions Code,  
6 to read:

7  
8 Article 7.5. Injectable Sterile Drug Products  
9

10 4127. The board shall adopt regulations establishing  
11 standards for compounding injectable sterile drug products in a  
12 pharmacy.

13 4127.1. (a) A pharmacy shall not compound injectable sterile  
14 drug products in this state unless the pharmacy has obtained a  
15 license from the board pursuant to this section. The license shall  
16 be renewed annually and is not transferable.

17 (b) A license to compound injectable sterile drug products may  
18 only be issued for a location that is licensed as a pharmacy.  
19 Furthermore, the license to compound injectable sterile drug  
20 products may only be issued to the owner of the pharmacy license  
21 at that location. A license to compound injectable sterile drug  
22 products may not be issued until the location is inspected by the  
23 board and found in compliance with this article and regulations  
24 adopted by the board.

25 (c) A license to compound injectable sterile drug products may  
26 not be renewed until the location has been inspected by the board  
27 and found to be in compliance with this article and regulations  
28 adopted by the board.

29 (d) Pharmacies operated by entities that are licensed by either  
30 the board or the State Department of Health Services and that have  
31 current accreditation from the Joint Commission on Accreditation  
32 of Healthcare Organizations, or other private accreditation  
33 agencies approved by the board, are exempt from the requirement  
34 to obtain a license pursuant to this section.

35 (e) The reconstitution of a sterile powder shall not require a  
36 license pursuant to this section if ~~all~~ *both* of the following are met:

37 (1) The sterile powder was obtained from a manufacturer.

38 (2) The drug is reconstituted for administration to ~~a specific~~  
39 ~~patient~~ *patients* by a health care professional licensed to  
40 administer drugs by injection pursuant to this division.

1 ~~(3) The reconstituted drug is immediately administered to the~~  
2 ~~patient.~~

3 (f) This section shall become effective on the earlier of July  
4 1, 2003, or the effective date of regulations adopted by the board  
5 pursuant to Section 4127.

6 4127.2. (a) A nonresident pharmacy may not compound  
7 injectable sterile drug products for shipment into the State of  
8 California without a license issued by the board pursuant to this  
9 section. The license shall be renewed annually and shall not be  
10 transferable.

11 (b) A license to compound injectable sterile drug products may  
12 only be issued for a location that is licensed as a nonresident  
13 pharmacy. Furthermore, the license to compound injectable sterile  
14 drug products may only be issued to the owner of the nonresident  
15 pharmacy license at that location. A license to compound  
16 injectable sterile drug products may not be issued or renewed until  
17 the board receives the following from the nonresident pharmacy:

18 (1) A copy of an inspection report issued by the pharmacy's  
19 licensing agency, or a report from a private accrediting agency  
20 approved by the board, in the prior 12 months documenting the  
21 pharmacy's compliance with board regulations regarding the  
22 compounding of injectable sterile drug products.

23 (2) A copy of the nonresident pharmacy's proposed policies  
24 and procedures for sterile compounding.

25 (c) Nonresident pharmacies operated by entities that are  
26 licensed as a hospital, home health agency, or a skilled nursing  
27 facility and have current accreditation from the Joint Commission  
28 on Accreditation of Healthcare Organizations, or other private  
29 accreditation agencies approved by the board, are exempt from the  
30 requirement to obtain a license pursuant to this section.

31 (d) This section shall become effective on the earlier of July 1,  
32 2003, or the effective date of regulations adopted by the board  
33 pursuant to Section 4127.

34 4127.3. (a) Whenever the board has a reasonable belief,  
35 based on information obtained during an inspection or  
36 investigation by the board, that a pharmacy compounding  
37 injectable sterile drug products poses an immediate threat to the  
38 public health or safety, the executive officer of the board may issue  
39 an order to the pharmacy to immediately cease and desist from  
40 compounding injectable sterile drug products. The cease and

desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4127.4. Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.

4127.5. The fee for the issuance of a license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).

4127.6. This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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